REMARKS

Claims 13-14, 16-17 and 19-23 are pending in this application.

I. THE CLAIM REJECTIONS UNDER 35 U.S.C. § 102(e) ARE IN ERROR AND SHOULD BE WITHDRAWN

1. The Present Invention

The presently claimed invention relates to a method of screening to identify a gene, whose function was unknown previously, as a target for drug development by using a combination of a high-density oligonucleotide array and *in situ* hybridization to identify those mRNAs and/or expression sequence tags ("ESTs") whose expression level and localization have both changed in response to an event. In said method, first, a high-density oligonucleotide array is used to examine the expression level of mRNAs and/or ESTs before and after an event and a scatter diagram is made to show the changes in expression levels (step (a)). Second, one or more mRNAs and/or ESTs whose expression level has changed in response to the event are identified based on the results in the scatter diagram and from databases searches (step (b)). Third, a probe that will specifically hybridize with the identified mRNA and/or EST whose expression level has changed in response to the event is designed (step (c)). Fourth, the probe is used to perform an *in situ* hybridization of at least two types of different tissues or cells of an organism before and after the event (step (d)). Fifth, the localization of the mRNA and/or EST in the tissues or cells is examined before and after the event (step (e)). Sixth, those mRNAs and/or ESTs whose localization has changed in response to the event are identified (step (f)). Finally, those mRNAs and/or ESTs whose expression level and localization have both changed in response to the event are identified as targets for drug development (step (g)). The present invention provides a novel, efficient and systemic method for screening and identifying genes with previously unknown functions that are useful for drug development.

2. Claims 13, 14, 16, 17 and 19-23 are Novel and Nonobvious Over Kingsman

Claims 13-14, 16-17 and 19-23 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Kingsman *et al.* (International Publication No. WO 01/62595 A2, "Kingsman"). For the following reasons, Applicant disagrees.

The legal test for anticipation under 35 U.S.C. § 102 requires that *each and every* element of the claimed invention be disclosed in a prior art reference in a manner sufficient to enable one skilled in the art to reduce the invention to practice, thus placing the public in

possession of the invention. *W.L. Gore Associates v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983) *cert. denied* 469 U.S. 851 (1984); *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985). Anticipation under 35 U.S.C. § 102 requires identity of invention. *Scripps Clinic & Research Fdn. v. Genentech Inc.*, 927 F.2d 1565, 18 USPQ2d 1001 (Fed. Cir. 1991).

Kingsman discloses a differential expression screening method for identifying a genetic element involved in a cellular process (see Kingsman, Abstract). In said method, first, gene expression is compared between a first cell and a second cell under at least two different environmental conditions relevant to the cellular process (see Kingsman, Abstract). Said second cell comprises a biological molecule implicated in the cellular process, the level of which is altered relative to physiological levels due to the presence of a heterologous nucleic acid directing expression of a polypeptide (see Kingsman, Abstract). Second, a genetic element whose expression differs between said first and second cells is identified. (see Kingsman, Abstract).

Applicant submits that Kingsman does not teach or suggest each and every element of claims 13-14, 16-17 and 19-23. The method of claim 13 comprises, *inter alia*, performing *in situ* hybridization to determine change in localization of the mRNAs and/or expression sequence tags in at least two types of tissues or cells of an organism before and after the event (*i.e.*, steps (d)-(g)). Kingsman never mentions the use of *in situ* hybridization as recited in step (d) of claim 13. In fact, Kingsman only discloses differential expression screening methods directed to screening gene expression, not localization as recited in claim 13. Specifically, Kingsman does not teach or suggest examining localization and determining whether the localization has changed as recited in steps (e) and (f) of claim 13, much less teach or suggest identifying genes or gene products whose expression and localization have both changed in the tissue or cells before and after an event as recited in step (g) of claim 13.

Because Kingsman fails to teach or suggest each and every element of claim 13 (*i.e.*, steps (d)-(g)), Applicant submits that the presently claimed invention comprises key features that are not anticipated by the disclosure of Kingsman. Claims 14, 16-17 and 19-23 are dependent on claim 13 and thus incorporate the limitations of claim 13. As such, they are also novel and nonobvious over Kingsman.

For the foregoing reasons, the Section 102(e) rejections are in error and Applicant respectfully requests that the rejections be withdrawn.

CONCLUSION

Applicant respectfully requests entry of the remarks made herein into the file history of the present application. Withdrawal of the Examiner's rejections and an allowance of the application are earnestly requested. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

Respectfully submitted,

by Ann Chen 49,013

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